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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,613	08/04/2000	Holly Hogrefe	04121.0116-07000	6689

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AGILENT TECHOLOGIES INC
P.O BOX 7599
BLDG E , LEGAL
LOVELAND, CO 80537-0599

EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
11/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com
maria_carroll@non.agilent.com
laurie_schutze@agilent.com

Office Action Summary	Application No.	Applicant(s)	
	09/631,613	HOGREFE ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 1007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69,70,72 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69,70,72 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/2007 has been entered. Claims 1-68, 71, 73 and 75-94 have been canceled. Claims 68, 70, 72 and 74 are pending and discussed in this Office action.

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 69, 70, 72 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim 69 is drawn to a method of enhancing a nucleic acid polymerase reaction comprising: forming a nucleic acid polymerase reaction composition comprising, (i) a nucleic acid; (ii) at least one nucleic acid polymerase selected from an archaeal nucleic acid polymerase and a modified archaeal nucleic acid polymerase; and (iii) a P45 protein, wherein the P45 protein is in monomeric, dimeric, or multimeric form, and wherein the p45 protein is produced from a cell containing a DNA construct comprising a sequence encoding polymerase enhancing factor protein p45 operably linked to an expression vector, and incubating the nucleic acid polymerase reaction composition under conditions allowing a nucleic acid polymerase reaction, wherein the P45 protein enhances the nucleic acid polymerase reaction. The claim 72 is drawn to a method for controlling the activity of a polymerase in a nucleic acid polymerase reaction, comprising: (a) forming a nucleic

acid polymerase reaction composition comprising: (i) a nucleic acid; (ii) at least one nucleic acid polymerase selected from an archaeal nucleic acid polymerase and a modified archaeal nucleic acid polymerase, and (iii) a polymerase enhancing factor activity, wherein the polymerase enhancing factor activity changes the amount of dUTP present or generated during the reaction, and (b) incubating the nucleic acid polymerase reaction under conditions allowing a nucleic acid reaction, wherein changing the amount of dUTP present or generated during the reaction control the activity of the polymerase in the polymerization reaction.

The limitation "an archaeal nucleic acid polymerase and a modified archaeal nucleic acid polymerase" encompasses a large genus of nucleic acid sequence not adequately described or disclosed. The specification teaches at 4, lines 1-4 that "Truncated Taq and T. Flavus DNA polymerase enzymes that apparently exhibit increase thermostability and fidelity in PCR have also been suggested (U.S. Patent 5,436,149)". The specification further teaches that "combinations of polymerases with and without 5' to 3' proofreading activity have also been used (US patent No. 5,489,523)". However, the specification does not teach wherein any archaeal nucleic acid polymerase or any truncation, or any modification of any archaeal nucleic acid polymerase is utilized to determine if it is enhanced in the presence of the p45 protein and/or PEF. Likewise, the specification does not teach or identify wherein any archaeal nucleic acid polymerase that has an altered proofreading function is utilized in the claimed method.

While the specification supports the use *Pfu* and Vent DNA polymerases, which are members of the archaeal nucleic acid polymerase being effective in the method as claimed, there is no support for the claim as broadly written. The specification does not support the plethora of modification of a nucleic acid polymerase, especially, archaeal nucleic acid polymerases, as encompassed by the claims. The specification does not provide any guidance for the selection of the infinite number of archaeal polymerases or modifications thereof that are encompassed by the instant invention as currently claimed or what properties or functions these infinite number of archaeal DNA polymerases would have in the instant method. Such limitation encompasses *any* nucleic acid change, variation, mutation or functional modification; none of which have been described.

A representative number of nucleic acid species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the modified species as claimed in claims 69, 70, 72 and 74 of the specification fails to show that Applicant was, in fact "in possession of the claimed invention" at the time the application for patent was filed.

Applicant's traversal and Examiner's Response

5. Applicant traverses the rejection on the ground that under US law, a claim satisfies the written description requirement of 35 USC 112 first paragraph is adequate

amount of information is provided by the application, taken into consideration with the state of the art, to indicate that the applicant was in possession of the claimed invention. Applicant cites several case laws and state that the Office does not cite any controlling statue or case law to support its position, but instead broadly asserts that the present application fails to disclose a representative number of modified species and thus lacks adequate written description of the claimed invention.

6. All of the arguments have been thoroughly reviewed and considered but are not found persuasive. In regards to Applicant's arguments concerning US laws concerning the written description requirement, the Examiner maintains that contrary to Applicant's arguments the specification does not conform to US law for adequate written description because the specification does not provide adequate information as all for the infinite number of DNA polymerases encompassed by the large genus of modified Archaeal DNA polymerases and claimed. The specification does not provide any structural characteristic for sequences of archeael DNA polymerases comprising any modification or mutation and does not provide any information that such sequences can be effectively enhanced using the instant invention. Still further Applicant fails to provide any evidence that the state of the art supports applicant's position. There is nothing in the instant specification which suggest that applicant was in possession of the undisclosed number of species for the broad genus at the time the instant applicant was filed. Therefore, this argument is not found persuasive.

In regards to Applicant's arguments that the Office has not provide any case law to support its position, the Examiner notes that there are numerous case laws which

supports the Examiner's position including those cited by Applicant. For example, Applicant states that Federal Circuit has said:

> Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

In this case, Applicant's invention as claimed do not meet these criteria because one cannot predict what sequence modification(s) fall within the scope of the claims. None of the members of the archaeal DNA polymerases disclosed in the instant specification or large family of DNA polymerases known in the art provides information for one to predict such changes. Further, Applicant is reminded to review *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, which states that the written description must convey to one of skill in the art *"with reasonable clarity"* that as of the filing date Applicant was in possession of the claimed invention. Applicant has not describe with reasonable clarity which firstly if in fact any modification of any member of the archeal DNA polyermase family is functional in the instant method. This argument is not found persuasive. Accordingly, the rejections are maintained.

Conclusion

7. No claims are allowed. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case.

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600